

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

IN THE CLAIMS

What is claimed is:

1. A drug release system comprising:
a bulk polymer phase;
a polymeric drug-enriched phase within the bulk polymer phase; and
at least one drug incorporated into the drug-enriched phase.
2. The drug release system of claim 1 wherein the drug-enriched phase comprises discrete, discontinuous sites within the bulk phase.
3. The drug release system of claim 1 wherein the drug-enriched phase comprises sites within the bulk phase that are discrete in cross-section but continuous in a longitudinal direction.
4. The drug release system of claim 1 wherein the drug-enriched phase comprises sites within the bulk phase that are continuous in both cross-section and in a longitudinal direction.
5. The drug release system of claim 1 wherein the bulk phase comprises a hydrophobic component and a hydrophilic component.
6. The drug release system of claim 1 wherein the bulk phase comprises poly(ethylene-co-vinyl)alcohol.
7. The drug release system of claim 1 wherein the bulk phase comprises polyethylene glycol.

8. The drug release system of claim 1 wherein the drug-enriched phase comprises polyethylene oxide and at least one drug.
9. The drug release system of claims 1 wherein the drug-enriched phase comprises poly n-vinyl pyrrolidone and at least one drug.
10. The drug release system of claim 1 wherein the drug-enriched phase has a glass transition temperature that is less than the temperature of the living human body.
11. The drug release system of claim 1 wherein the drug-enriched phase has drug concentration that is greater than the percolation threshold.
12. The drug release system of claim 5 wherein the bulk phase comprises poly(ethylene-co-vinyl) alcohol with ethylene groups in a concentration of 66 weight percent, vinyl alcohol groups and vinyl ether groups in a concentration of about 0.68 percent by weight.
13. The drug release system of claim 9 wherein the drug-enriched phase reacts with the vinyl ether groups of the bulk phase to form a urethane linkage.
14. The drug release system of claim 10 wherein the drug-enriched group comprises polyethylene oxide-isocyanate.
15. The drug release system of claim 13 wherein the urethane linkage comprises about 33 weight percent of the drug release system.
16. The drug release system of claim 1 wherein the drug comprises Actinomycin D.

17. The drug release system of claim 1 wherein the drug comprises one or more of an antiproliferative substance, an antineoplastic substance, an anti-inflammatory, anti-platelet, anticoagulant, antigranulocyte, antithrombin, antimitotic, antibiotic, antioxidant and combinations of these substances.
18. A coating comprising the drug release system of claim 1.
19. The coating of claim 18 wherein the bulk phase polymer is deformable but is not deformable to the touch and wherein the coating has a uniform appearance at room temperature.
20. The coating of claim 18 and further comprising an implantable device to which the coating is applied.
21. The coating of claim 20 wherein the implantable device is a catheter or a stent or a guidewire.
22. A method for substantially continuously releasing drugs, comprising:
applying the drug delivery system of claim 1 to an implantable medical device; and
transporting the drug delivery system and the implantable medical device to a treatment site wherein the drug delivery system releases one or more drugs.
23. The method of claim 22 wherein the implantable device comprises degradable capsules.
24. A device for continuously releasing drugs, comprising:
a drug release system comprising a bulk polymer phase;
a drug-enriched polymeric phase within the bulk polymer phase; and

at least one drug incorporated into the drug-enriched phase wherein the drug-enriched phase comprises sites within the bulk phase that are continuous in both cross-section and in a longitudinal direction; and an implantable device to which the drug release system is applied.

25. The device of claim 24 wherein the implantable device is a guidewire.
26. The device of claim 24 wherein the implantable device comprises degradable capsules.
27. The device of claim 24 wherein the implantable device comprises a catheter.
28. The device of claim 24 wherein the bulk phase comprise poly(ethylene-co-vinyl)alcohol.
29. The device of claim 24 wherein the drug-enriched phase comprises polyethylene oxide and at least one drug.
30. The device of claim 24 wherein the drug-enriched phase has a glass transition temperature that is less than the temperature of the living human body.
31. The device of claim 24 wherein the drug-enriched phase has a drug concentration that is greater than the percolation threshold.
32. The device of claim 24 wherein the drug release system is flexible.
33. The device of claim 24 wherein the drug release system has a generally uniform appearance.
34. A method for making a device for a continuous release of drugs, comprising:

providing a bulk phase polymer;
providing at least one drug that is substantially insoluble in the bulk phase polymer;
providing a drug enrichable polymer wherein the drug enrichable polymer is substantially insoluble in the bulk polymer and wherein the drug is soluble in the drug-enrichable polymer;
providing a solvent; and
blending the bulk phase polymer, the drug enrichable polymer, and the drug in the solvent so that the drug is incorporated into the drug enrichable polymer and the drug enrichable polymer is dispersed within the bulk polymer to make the device.

35. The method of claim 34 and further comprising blending at a temperature that is less than the glass transition temperature of the drug enrichable polymer.
36. The method of claim 34 and further comprising blending at a concentration of drug enrichable polymer that is greater than the percolation threshold.
37. The method of claim 34 and further comprising blending to form a semi-continuous phase of drug enrichable polymer in the bulk polymer.
38. The method of claim 34 and further comprising blending to form a continuous phase of drug enrichable polymer in the bulk polymer.
39. The method of claim 34 wherein the solvent comprises one or more of dimethyl sulfoxide or N,N-dimethylacetamide.
40. The method of claim 34 wherein the drug comprises actinomycin D.

41. The method of claim 34 and further comprising applying the device for continuous release of drugs to an implantable device.
42. The method of claim 41 and further comprising drying the device for continuous release of drugs so that the device is flexible.
43. The method of claim 42 wherein the device for continuous release of drugs has a visually uniform appearance